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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,852	12/31/2001	Ronald B. Hopkins	RHOP 2	5318

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John H Thomas PC
1561 East Main Street
Richmond, VA 23219

EXAMINER


ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/029,852	Applicant(s) HOPKINS ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-12 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated April 12, 2004. Claims 1-5 and 7-12 are pending.

Response to Arguments

1. Applicant's arguments filed April 12, 2004 have been fully considered but they are not persuasive.

Applicant initially states, "The Examiner 'bears the initial burden, of review of the prior art...,of presenting a prima facie case of unpatentability.' In re Oetiker, 977 F. 2d 1443, 1145 (Fed. Cir. 1992)." The examiner fully agrees with this statement and has thoroughly examined the case on its merits. Applicant then cites numerous lines of case law.

Applicant also provides medical references discussing the elbow and supination and pronation of the forearm. However, supination and pronation are broad terms that define movement of various anatomical features. Supination and pronation are not limited to the elbow. Supination is defined as to turn (the hand and forearm) so that the palm is upward or forward; to turn (the foot or leg) so that the sole is outward according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Meanwhile, pronate is defined as to turn or rotate (the hand or forearm) so that the palm faces down or back; to turn or rotate (the sole of the foot) by abduction and eversion so that the inner edge of the sole bears the

body's weight; to turn or rotate (a limb) so that the inner surface faces down or back according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Given these definitions, applicant's attention is directed to claim 1 (for example), which recites, wherein a ***rotation force of supination or pronation will be created on the forearm enclosure*** depending on the direction which the tensioning member is extended from the anchor to the post." This is the only limitation in claim 1 that discusses supination and pronation. This supination and pronation is only discussed relative to a rotation force on the ***forearm enclosure***. It appears that applicant is arguing features that are not claimed. Moreover, applicant is reminded that functional language does not hold patentable weight in apparatus claims. Applicant has not defined structure that would define over the prior art of record. It has been held that functional "wherein" and "whereby" statements that do not define any structure cannot serve to distinguish. In re mason, 114 USPQ 127, 44 CCPA 937 (1957). "Wherein" and "whereby" statement are considered "[l]anguage that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure [and therefore] does not limit the scope of a claim or claim citation." (See M.P.E.P. 2106, page 2100-7, Rev. 2, July 1996). Thus, as long as the structure is **capable** of performing the function it meets the limitation. Thus, the claim is not directed or limited to supination and pronation that is a function of the elbow. Applicant's incorporation of that disclosed in claim 6 into claim 1 does not define structure that would

define over the prior art. Applicant's statement, "Further, the claims have been amended to emphasize the elbow function by including the upper arm support member which is required to obtain the proper supination/pronation function of the elbow." The upper arm support is shown in Doran and functional language does not hold patentable weight in apparatus claims.

Regarding applicants argument that Doran does not disclose a forearm support member **adapted** to slidably receive a forearm enclosure, the screw slides and there is clear adjustment. Further, the term "adapted" is functional. There is not a positive recitation of slidable to define over the prior art.

Applicant has failed to define structural features that define over the prior art of record. Functional/method terminology is not given patentable weight in apparatus claims.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 4, 7, and 10-12 are rejected under 35 U.S.C. 102(a and/or e)/103(a) as being anticipated by Doran in US Patent No. 6,179,799.

Regarding claim 1, Doran discloses an orthotic device (10) for promoting supination and pronation having a forearm enclosure (26 and via straps such as 27) adapted to *substantially* wrap around a forearm, as seen in figures 1-3; a forearm support member (such as 30, 33, etc. and associated components) adapted to slidably receive the forearm enclosure (as recited in column 3) wherein the support member (portion at 70) wraps *partially* around the forearm enclosure (at connection of 70 and 26); and a tensioning member (such as 71A, 71B), wherein a rotational force of supination or pronation will be created on the forearm enclosure depending on the direction which the tensioning member is extended, as recited in column 3, lines 2-4, with emphasis on column 3, lines 44-55 and seen in figure 3. Although a post mounted on the forearm enclosure, an anchor mounted on the support member, wherein the tensioning member is connected on one end to the anchor and on the other end to the post is not explicitly recited, it is inherent that a connection is required. Thus, given a reasonably broad interpretation of post and anchor the connection means of Doran can be considered inherently a post and anchor.

Further, given a reasonably broad interpretation of a forearm enclosure and support member, the invention of Doran would read on the claim limitation. However, Hamersly in US Patent No. 5,683,353 has been cited below for a structure that more closely resembles that shown in the figures of the current application, and thus, would also be considered obvious.

Doran also discloses an upper arm support member (such as that at 25) connected on one end to the forearm support member and adapted to substantially wrap around and support an upper arm, as seen in figure 1.

Regarding claim 3, Doran discloses that as applied to claim 1, as well as, a tensioning member that is an elastic material, as recited in column 3, lines 44-55.

Regarding claim 4, Doran discloses that as applied to claim 1, as well as, a tensioning member that is of an inelastic material, as recited in column 3, lines 44-55.

Regarding claim 7, Doran discloses that as applied to claim 1, as well as, an upper arm support member that is hingedly connected to the forearm support member, as recited in column 2, lines 45-50.

Regarding claim 10, Doran discloses that as applied to claim 7, as well as, an angle of connection of the upper arm support member and the forearm support member that is variable, as recited in column 2.

Regarding claim 11, Doran discloses an orthotic device (10) for promoting supination and pronation having a forearm enclosure (such as 26 and via straps such as 27) adapted to *substantially* wrap around a forearm; a forearm support member (such as 30, 33, etc. and associated components) adapted to slidably receive the forearm

enclosure wherein the support member wraps *partially* around the cast (as recited in column 3); tensioning means (71A, 71B) having a first and a second end; and means for attaching the tensioning means on the first end to the forearm enclosure and on the second end to the forearm support member, wherein a rotational force of supination or pronation will be created on the forearm enclosure depending on the direction which the tensioning means is attached to the forearm support member and the forearm enclosure, as recited in column 3, lines 2-4, with emphasis on column 3, lines 44-55 and seen in figure 3. Further, it is necessary to have an attachment. Doran also discloses an upper arm support member (such as that at 25) connected on one end to the forearm support member and adapted to substantially wrap around and support an upper arm, as seen in figure 1.

Regarding claim 12, Doran discloses a forearm enclosure (such as 26 and via straps such as 27) adapted to *substantially* wrap around a forearm; a forearm support member (such as 30, 33, etc. and associated components) adapted to slidably receive the forearm enclosure (as recited in column 3), wherein the support member is adapted to wrap *partially* around the forearm enclosure; and a tensioning member (71A, 71B). Although a post mounted on the forearm enclosure, an anchor mounted on the support member, wherein the tensioning member is connected on one end to the anchor and on the other end to the post is not explicitly recited, it is inherent that a connection is required. Thus, given a reasonably broad interpretation of post and anchor the connection means of Doran can be considered inherently a post and anchor. Doran

also discloses an upper arm support member (such as that at 25) connected on one end to the forearm support member and adapted to substantially wrap around and support an upper arm, as seen in figure 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 5, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doran in US Patent No. 6,179,799.

Regarding claim 2, Doran discloses that as applied to claim 1. However, Doran do not explicitly recite a plurality of posts mounted at different locations on the forearm enclosure. On the other hand, it would be obvious to one with ordinary skill in the art to have multiple attachment locations for the purpose of adjusting tension.

Regarding claim 5, Doran discloses that as applied to claim 1. However, Doran do not explicitly recite a tensioning member that has an adjustable length. On the other hand, it would also be obvious to one with ordinary skill in the art to make the tensioning member be adjustable for it has been held that it only requires routine skill in the art to make something formerly not adjustable, adjustable.

Regarding claim 8, Doran discloses that as applied to claim 6. However, Doran do not explicitly recite an upper arm support member is fixedly connected to the forearm support member at a predetermined angle. However, the specification of the current application does not demonstrate the criticality of an upper arm support member is fixedly connected to the forearm support member at a predetermined angle. Further, claims are drawn to a support member that is hingedly connected. Thus, a fixed and hinged attachment can be considered equivalents.

Regarding claim 9, Doran as modified discloses that as applied to claim 8. However, Doran do not explicitly recite a predetermined angle that is substantially 90. However, the specification of the current application does not demonstrate the criticality of a predetermined angle that is substantially 90. Further, claims are drawn to an angle that is varied. Thus, a predetermined angle that is substantially 90 can be considered an equivalent to the variable angle.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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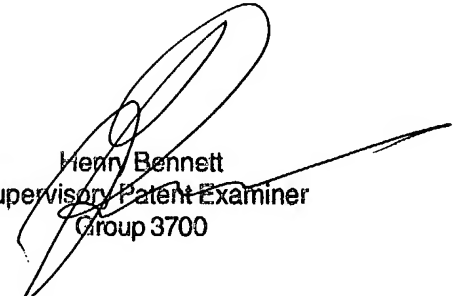
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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